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FIRST NAMED INVENTOR APPLICATION NO. FILING DATE ATTORNEY DOCKET NO. CONFIRMATION NO. 155696-0034 5788 09/973,280 10/08/2001 Alex Urich EXAMINER 03/11/2005 1622 7590 LAM, ANN Y **IRELL & MANELLA LLP** 840 NEWPORT CENTER DRIVE ART UNIT PAPER NUMBER SUITE 400 NEWPORT BEACH, CA 92660

1641 DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)		
		09/973,280	URICH, ALEX	4	
Office Action Summary		Examiner	Art Unit		
	•	Ann Y. Lam	1641		
	The MAILING DATE of this communic			ess	
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).					
Status					
1)⊠	Responsive to communication(s) filed on <u>13 December 2004</u> .				
<i>'</i>		b)☐ This action is non-final.			
3)□					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims					
<ul> <li>4)  Claim(s) 1,3,4,6,8,9,11,13,14,16,18,19 and 21 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) 1,3,4,6,8,9,11,13,14,16,18,19 and 21 is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) are subject to restriction and/or election requirement.</li> </ul>					
Application Papers					
9)☐ The specification is objected to by the Examiner.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.					
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.					
Priority under 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some color None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.					
Attachment(s)					
1) Notice 2) Notice 3) Inform	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PT nation Disclosure Statement(s) (PTO-1449 or P · No(s)/Mail Date	O-948) Paper N	w Summary (PTO-413) lo(s)/Mail Date of Informal Patent Application (PTO-1	52)	

### **DETAILED ACTION**

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1, 11 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saaski et al., 5,585,011.

Saaski et al. discloses the invention substantially as claimed.

As to claims 1 and 11, Saaski et al. discloses a pump (130), and a non-linear flow restrictor (86) coupled to said pump, see Figure 10 or 11, said non-linear flow restrictor has a plurality of bends that change the direction of fluid flow to create a non-linear relationship between a fluid pressure and a fluid fowrate (column 30, lines 38-45.)

As to claim 21, Saaski et al. discloses a method comprising creating a flow of fluid that has a pressure and a flowrate, see column 4, lines 12-39; and restricting the flow of fluid in a tube by changing a direction of fluid flow a plurality of times so that a variation in the pressure will create a non-linear change in the flowrate, see column 30, lines 34-45.

However, Saaski et al. does not disclose that the non-linear flow restrictor has an effective length of at least eight feet.

Saaski et al. however does teach that although the device as illustrated in the examples are very small, it is understood that, by applying scaling laws, the device may in general be scaled up to any desired size, to handle any desired fluid flow rate and pressure (col. 10, lines 56-62.) Also, Saaski et al. teaches that "for any given length of channel 86 and regulator seat 90, such courses may permit the manufacture of a linear regulator 80 which is more compact, as compared to a linear regulator 80 having a straight channel 86 and regulator seat 90."

Moreover, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

In this case, Saaski et al. teaches the general conditions of the claim, and the claimed range of length of the non-linear flow restrictor is an optimum or workable range, and thus involves only routine skill in the art.

2. Claims 3 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saaski et al., 5,585,011, in view of Nun, 6,217,584.

Saaski discloses the invention substantially as claimed (see above). More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30),

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but does not specifically disclose an embodiment wherein the pump is a peristaltic pump. Saaski however states that the described invention is by way of non-limiting example, and that modifications, adaptations and variations apparent to those skilled in the art are within the scope of the disclosure, column 101, lines 4-11.

Nun, similar to Saaski, discloses a fluid handling device (204) connected to a pump (column 12, line 8.) Nun specifically teaches that the pump may be a peristaltic pump to regulate the flow of fluid (column 12, lines3-8.)

It would have been obvious to one of ordinary skill to substitute the peristaltic pump taught by Nun for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

3. Claims 4 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saaski et al., 5,585,011, in view of Cochran et al., 5,910,139.

Saaski discloses the invention substantially as claimed (see above). More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30.) However, Saaski does not specifically disclose that the pump may be a venturi pump.

Cochran, similar to Saaski, discloses a medical device (col. 17, line 19-24) connected to a pump (col. 17, line 29.) Cochran further discloses that the pump may be a venturi pump (column 17, line 29.)

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It would have been obvious to one of ordinary skill to substitute the venturi pump taught by Cochran for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

**4.** Claims 6, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anis et al., 5,911,699, in view of Saaski et al., 5,585,011.

Anis discloses the invention substantially as claimed.

More specifically, Anis discloses a device comprising:

handpiece (10);

a cutting element (17A) attached to said handpiece;

a pump or pump means (column 6, line 46) coupled to said handpiece.

Anis teaches that the device is used to remove tissue from the body such as for example removal of cataracts from the eye, (col. 1, lines 19-20.) Although Anis discloses that the device includes a pump mechanism for irrigating fluid (col. 6, line 46), Anis does not disclose a non-linear flow restrictor or flow restrictor means coupled to the pump and handpiece, wherein the non-linear flow restrictor has a plurality of bends that change the direction of fluid flow to create a non-linear relationship between a fluid pressure and a fluid.

Saaski teaches a flow regulator that may be used to control the flow rate of a fluid medication (col. 12, lines 52-53.) Saaski discloses that one aspect of the invention

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is to provide fluid handling devices that are capable of continually handling fluids over an extended period of time at relatively low flow rates (col. 1, lines 36-39.) Saaski also discloses that another aspect of the invention is to provide fluid handling devices which are small (col. 1, lines 42-46.) Saaski further discloses that another aspect of the invention is to provide a fluid handling device in the form of a flow regulator which will maintain the flow of the medication within predetermined parameters, despite fluctuations in the pressure of the medication (col. 2, line 66 – col. 3, line 3.) Saaski does not limit the device to a particular medical device or procedure, but refers to a fluid handling device as it applies to many different medical situations (col. 1, lines 20 and 42; col. 2, lines 10, 44 and 56.) Saaski further states that the described invention is by way of non-limiting example, and that modifications, adaptations and variations apparent to those skilled in the art are within the scope of the disclosure, column 101, lines 4-11.

Since the Anis apparatus is a fluid handling device with a pump, and Saaski teaches a flow regulator that provides advantages to a fluid handling device with a pump, it would have been obvious to one of ordinary skill in the art to provide the flow regulator taught by Saaski in the Anis invention in order to allow for the Anis pump to continually handle fluids over an extended period of time at low flow rates, or to provide for a fluid handling device that is small, or to maintain the flow of irrigation within predetermined parameters, as taught by Saaski, as would be desirable in the Anis invention in irrigating fluid during surgery.

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5. Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anis et al., 5,911,699, in view of Saaski et al., 5,585,011, as applied to claims 6 and 16, and further in view of Nun, 6,217,584.

The invention as claimed is substantially disclosed by Anis in view of Saaski (see above with respect to claims 6 and 16.) More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30), but does not specifically disclose an embodiment wherein the pump is a peristaltic pump. Saaski however states that the described invention is by way of non-limiting example, and that modifications, adaptations and variations apparent to those skilled in the art are within the scope of the disclosure, column 101, lines 4-11.

Nun, similar to Saaski and Anis, discloses a fluid handling device (204) connected to a pump (column 12, line 8.) Nun specifically teaches that the pump may be a peristaltic pump to regulate the flow of fluid (column 12, lines3-8.)

It would have been obvious to one of ordinary skill to substitute the venturi pump taught by Nun for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

6. Claims 9 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anis et al., 5,911,699, in view of Saaski et al., 5,585,011, as applied to claims 6 and 16, and further in view of Cochran et al., 5,910,139.

The invention as claimed is substantially disclosed by Anis in view of Saaski (see above with respect to claims 6 and 16). More specifically, Saaski discloses a non-linear flow restrictor and a pump. Saaski discloses an embodiment wherein the pump is a piezo-electric motor pump (col. 4, lines 29-30.) However, Saaski does not specifically disclose that the pump may be a venturi pump.

Cochran, similar to Saaski and Anis, discloses a medical device (col. 17, line 19-24) connected to a pump (col. 17, line 29.) Cochran further discloses that the pump may be a venturi pump (column 17, line 29.)

It would have been obvious to one of ordinary skill to substitute the peristaltic pump taught by Cochran for the piezo-electric motor pump in the Saaski device since both pumps are conventional pumps for regulating the flow of fluid, and it is well known in the art that one conventional pumping means can be substituted for another.

# Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection. As indicated above, Saaski et al. discloses that the device can be scaled to any size, and moreover according to *In re Aller*, the discovery of the claimed range of length of the non-linear flow restrictor, which is an optimum or workable range, involves only routine skill in the art.

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### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.

LONG V. LE SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

03/07/05